

## SETTLEMENT AGREEMENT

This Settlement Agreement (Agreement) is entered into among the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General (OIG-HHS) of the Department of Health and Human Services (HHS), the Department of Defense's Defense Health Agency (DHA) on behalf of the TRICARE program, and the United States Office of Personnel Management (OPM), which administers the Federal Employees Health Benefits Program (FEHBP) (collectively the "United States"), Health Diagnostic Laboratory, Inc. (HDL), and Dr. Michael Mayes, Chris Riedel, Scarlett Lutz, and Kayla Webster (collectively, "Relators") (hereafter collectively referred to as "the Parties"), through their authorized representatives.

### RECITALS

A. HDL is a privately-held laboratory company headquartered in Richmond, Virginia, which, at all relevant times, provided laboratory testing services for patients referred by physicians and other health care providers.

B. Relators filed the following actions pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b):

*United States ex rel. Riedel v. Health Diagnostic Laboratory, Inc., et al.,*  
Case No. 1:11-CV-02308 (D.D.C.)

*United States ex rel. Mayes v. Berkeley HeartLab Inc., et al.,* Case No.  
9:11-CV-01593-RMG (D.S.C.)

*United States et al. ex rel. Lutz et al. v. Health Diagnostic Laboratory,*  
Inc., et al., Case No. 9:14-CV-0230-RMG (D.S.C.).

In addition, a fourth *qui tam* action, *United States et al. ex rel. [UNDER SEAL] v. [UNDER SEAL]* was also filed against HDL. Collectively, these actions are referred to herein as the “Civil Actions.”

Relators allege that HDL submitted claims for payment to federal healthcare programs that were not reimbursable because they were tainted by kickbacks and/or were for medically unnecessary services.

C. The United States contends that HDL submitted claims for payment to the Medicare Program (Medicare), Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk-1; the TRICARE Program, 10 U.S.C. §§ 1071-1110b; the Medicaid Program (Medicaid), 42 U.S.C. §§ 1396-1396w-5; and FEHBP, 5 U.S.C. §§ 8901-8914 (collectively, “Government Healthcare Programs”).

D. The United States contends that it has certain civil claims against HDL for engaging in the following conduct during the period of November 25, 2008, through January 31, 2015 (hereinafter, the “Covered Conduct”):

- (1) offering and/or paying illegal remuneration to health care providers through “process and handling” payments related to the collection of blood; speaker programs; advisory boards; consulting arrangements; goods and services; and gifts, which remuneration was intended, in whole or in part, to induce referrals in violation of the Anti-Kickback Statute (AKS), 42 U.S.C. § 1320a-7b(b), the Prohibition Against Certain Physician Self-Referrals (the Stark Law), 42 U.S.C. § 1395nn, or both;
- (2) routinely offering to waive and/or waiving cost-sharing obligations, such as copayments and deductibles, for certain TRICARE beneficiaries, with the intent, in whole or in part, to induce referrals to HDL for testing, in violation of the AKS;
- (3) submitting or causing to be submitted claims for payment to the Government Healthcare Programs for tests that were not medically necessary or that were not appropriately coded; and
- (4) offering and/or paying illegal remuneration in the form of commission payments to BlueWave Healthcare Consultants, Inc. (BlueWave), pursuant to a Sales Agreement between HDL and BlueWave, to induce BlueWave to arrange or

recommend the referral of beneficiaries of Government Healthcare Programs to HDL for testing, in violation of the AKS.

As a result of the foregoing conduct, the United States alleges that HDL is liable for knowingly submitting false or fraudulent claims to Government Healthcare Programs, in violation of the False Claims Act (FCA), 31 U.S.C. §§ 3729-3733. The United States contends also that, in conjunction with the conduct described in this Paragraph, HDL is liable for conspiring to submit false or fraudulent claims to Government Healthcare Programs, also in violation of the FCA.

E. HDL has entered or will be entering into separate settlement agreements with certain states and the District of Columbia in settlement of the Covered Conduct (the "Medicaid State Settlement Agreements"). States with which HDL executes a Medicaid State Settlement Agreement in the form to which HDL and the National Association of Medicaid Fraud Control Units (NAMFCU) have agreed, or in a form otherwise agreed to by HDL and an individual State, constitute the "Participating Medicaid States."

F. HDL denies the allegations of the United States set forth herein and the allegations made in the Civil Actions. This Agreement is neither an admission of liability by HDL nor a concession by the United States that its claims are not well founded.

G. Relators claim entitlement under 31 U.S.C. § 3730(d) to a share of the proceeds of this Agreement and to Relators' reasonable expenses, attorneys' fees and costs.

To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the above claims, and in consideration of the mutual promises and obligations of this Agreement, the Parties agree and covenant as follows:

## TERMS AND CONDITIONS

1. HDL shall make the following payments, hereinafter collectively referred to as the "Settlement Amount," to the United States and the Participating Medicaid States as follows: by electronic funds transfer, pursuant to written instructions to be provided by the Department of Justice's Civil Division to HDL on the Effective Date; and to the Participating Medicaid States by electronic funds transfer pursuant to written instructions from the NAMFCU Negotiating Team and under the terms and conditions of the Medicaid State Settlement Agreements:

- a. Fixed Payments. HDL shall pay to the United States and the Participating Medicaid States \$47 million in fixed payments (Fixed Settlement Amount), plus interest accrued on the unpaid portion thereof at the rate of 2.25% per annum, in accordance with the payment schedule attached hereto as Exhibit A. On the Effective Date of this Agreement, this sum shall constitute a debt due and owing to the United States and the Participating Medicaid States per the terms of Exhibit A. The entire balance of the Fixed Settlement Amount, or any portion thereof, plus any interest accrued on the principal as of the date of any prepayment, may be prepaid without penalty. Unless otherwise agreed by HDL and the United States, any prepayment shall be applied to the amounts due on the next payment date, with the excess, if any, applied to amounts due on each succeeding payment date thereafter.
- b. Contingent Payments. Upon the occurrence of the following contingencies, HDL shall pay to the United States and the Participating Medicaid States the following amounts (each, a Contingent Payment) on the terms and conditions set forth below. The United States and the Participating Medicaid States shall receive a pro rata share of any Contingent Payments made under this Agreement as specifically set forth herein: HDL shall pay the United States 99.56 percent of any Contingent Payments, and HDL shall pay the Participating Medicaid States collectively 0.44 percent of any Contingent Payments. Any Contingent Payments are in addition to the Fixed Payments provided for in Paragraph 1.a. For purposes of this Paragraph 1.b, the term "Net Proceeds" means the amount received by the seller after all sales costs (i.e., commissions, appraisals, sales-related taxes and attorneys' fees) and debts that are not assumed by the buyer are deducted from the gross proceeds arising from the sale of an asset.
  - i. Building/Property Sale. HDL shall, within five years following the Effective Date of this Agreement, pay to the United States an amount equal to 75% of the Net After-Tax Proceeds of any

sale or deemed sale of the real property located at 757 N. 5<sup>th</sup> Street, Richmond, Virginia 23219-1441 (the "Property"). HDL's payment to the United States under this Paragraph 1.b.i will take place within thirty (30) days of such sale or deemed sale. For purposes of this Paragraph 1.b.i., the term "Net After-Tax Proceeds" means the amount received by HDL from the Net Proceeds of a sale or deemed sale of the Property, less the sum of all taxes owed by HDL on any gain or other income arising from such sale or deemed sale. The Parties agree that a sale of the Property shall be deemed to have occurred if HDL Properties, LLC sells its ownership interest in Biotech 8, LLC or HDL sells its ownership interest in HDL Properties, LLC. If, for any reason (including, without limitation, any restrictions that may be imposed by the organizational documents of Biotech 8, LLC), no sale or deemed sale of the Property has occurred within four years of the Effective Date, HDL may satisfy its obligations under this Paragraph 1.b.i by obtaining an appraisal of the Property by an independent third-party appraiser mutually agreed to by HDL and the United States and paying to the United States and the Participating Medicaid States, not later than the date that is five years from the Effective Date, an aggregate amount equal to 75% of the Net After-Tax Proceeds derived from a deemed sale of the Property at the appraised value. Prior to any sale or deemed sale, HDL will use its best efforts to cause Biotech 8, LLC to maintain the Property, to pay property taxes, and to prevent any encumbrances on the Property other than encumbrances arising in the ordinary course of business or existing encumbrances and any renewals or replacements thereof.

ii. Sale Contingency.

- A. If, within five years following the Effective Date of this Agreement, HDL is merged into, sold, or otherwise transferred to any person or entity other than a wholly-owned subsidiary of HDL, HDL shall pay to the United States and the Participating Medicaid States an aggregate amount equal to 10% of the Net Proceeds of such sale, merger, or transfer within thirty (30) days of the date such transaction is closed.
- B. If, within five years following the Effective Date of this Agreement, HDL closes a Subject Asset Sale, HDL shall pay to the United States and the Participating Medicaid States an aggregate amount equal to 10% of the Net Proceeds of such Subject Asset Sale; provided

that (1) the sale or deemed sale of the Property pursuant to Paragraph 1.b.i hereof shall not constitute a Subject Asset Sale, and (2) the sale, merger or other transfer of any Excluded Asset within the first two years following the Effective Date shall not constitute a Subject Asset Sale and no amounts will be payable from the Net Proceeds thereof. Any payments made under this provision will be within thirty (30) days of the date such transaction is closed.

For purposes of this Paragraph 1.b.ii, "Subject Asset Sale" means a sale, merger or other transfer of an asset to or into a person or entity other than a wholly-owned subsidiary of HDL outside the ordinary course of business that generates Net Proceeds on a cumulative basis in excess of \$2.5 million, and "Excluded Asset" means the equity or assets of any or all of the following entities: Central Medical Laboratory, LLC (CML); Innovative Diagnostic Laboratory, LLP (IDL); Global Genomics Group, LLC (G3); and Global Institute for Research, LLC (GIR).

- iii. Revenue Contingency. If, in any of the next five fiscal years, HDL generates Excess Net Annual Revenue, as defined in the agreed schedule that will be separately delivered by HDL to the United States on the Effective Date of this Agreement, HDL agrees that it shall pay the United States an amount equal to 10% of such Excess Net Annual Revenue. Within one hundred twenty (120) days of the close of each of the next five fiscal years, beginning with fiscal year 2015, HDL shall deliver to the United States a copy of its audited financials and a letter stating whether HDL has generated any Excess Net Annual Revenue in such fiscal year and in what amount. Any payment owing under this provision shall be contemporaneously made to the United States with the delivery of the audited financials and calculation statement for such fiscal year. Together, HDL's deliverables of the agreed schedule, the audited financials, and letters pertaining to the Excess Net Annual Revenue constitute "HDL Financial Representations" that, because of the sensitive and proprietary nature of the information contained therein, are subject to the terms and conditions of the May 14, 2013 Confidentiality Agreement between HDL and the United States, as amended.
- c. Cap. In no event shall HDL be required to make aggregate payments under this Paragraph 1 in excess of \$100 million (the "Settlement Cap"), whether in the form of the Fixed Settlement Payment, Contingent Payments, or interest. After HDL makes aggregate payments under this Paragraph 1 in an amount equal to the

Settlement Cap, it shall have no further payment obligations under this Agreement to the United States, the Participating Medicaid States, or the Relators.

d. Acceleration Clause. If, within five years following the Effective Date of this Agreement, HDL is, or substantially all of HDL's assets are, merged into, or sold or transferred to an entity other than a wholly-owned subsidiary, then HDL shall promptly notify the United States, and all remaining payments owed pursuant to the Agreement shall be accelerated and become immediately due and payable. If no sale or deemed sale of the Property has occurred, and the Property is included in such sale, the amount payable pursuant to Paragraph 1.b.i shall be determined in accordance with the appraisal process set forth therein.

2. Default. In the event that HDL fails to pay any amount as provided in Paragraph 1 within five (5) business days of the date on which such payment is due, HDL shall be in default of its payment obligations (Default). The United States will provide written notice of the Default to HDL and HDL shall have the opportunity to cure such Default within ten (10) business days from the date of receipt of the notice. If HDL fails to cure such Default within ten (10) business days of receiving the Notice of Default (such failure, an "Event of Default"), the remaining unpaid balance of the Settlement Amount shall become immediately due and payable, and interest shall accrue at the rate of 12% per annum compounded daily from the date of Default on the remaining unpaid total (principal and interest balance). The Parties agree that, in the event of a dispute over the amount of a Contingent Payment due hereunder, no Default or Event of Default shall have occurred if HDL has paid the undisputed portion of such Contingent Payment within the times specified in Paragraph 1 or this Paragraph 2. Upon the occurrence of an Event of Default, HDL agrees to the entry of a consent judgment in the amount of the Settlement Cap (i.e., \$100 million), plus interest at the rate of 12% per annum on the unpaid balance as of the date of the Event of Default ("Consent Judgment"). All amounts paid by HDL pursuant to this Agreement shall be credited against the principal balance of

the Consent Judgment, except that any interest paid as a result of an Event of Default shall be in addition to the amounts paid pursuant to Paragraphs 1 and 2, and shall not be subject to the Cap set forth in Paragraph 1.c. Moreover, the United States may, at its sole option, offset any portion of the remaining unpaid balance from any amounts due and owing to HDL by any department, agency, or agent of the United States at the time of Default and/or the exercise of any other rights granted by law or in equity, including referral of this matter for private collection. HDL agrees not to contest any consent judgment, offset, or any collection action undertaken by the United States pursuant to this Paragraph, either administratively or in any state or federal court, and HDL shall pay the United States all reasonable costs of collection and enforcement under this Paragraph, including attorneys' fees and expenses due to outside counsel.

3. Subject to the exceptions in Paragraph 8 (concerning excluded claims) and conditioned upon HDL's full payment of the Settlement Amount as set forth in Paragraph 1, above, and subject to Paragraphs 2 (concerning Default), 21 and 22 (concerning bankruptcy proceedings commenced within 91 days of the Effective Date of this Agreement or any payment made under this Agreement), the United States releases HDL and its successors from any civil or administrative monetary claim the United States has or may have for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; or the common law theories of payment by mistake, unjust enrichment, fraud, and disgorgement.

4. Subject to the exceptions in Paragraph 8 (concerning excluded claims) below, and conditioned upon HDL's full payment of the Settlement Amount as set forth in Paragraph

1, above, and subject to Paragraphs 2 (concerning Default), 21 and 22 (concerning bankruptcy proceedings commenced within 91 days of the Effective Date of this Agreement or any payment made under this Agreement). Relators, for themselves and for their heirs, successors, attorneys, agents, and assigns, and any other person or entity acting on their behalf or asserting their rights, release HDL, together with its successors, from any civil monetary claim the Relators have on behalf of the United States for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733, and from all liability claims, demands, actions or causes of action, whether known or unknown, fixed or contingent, in law or in equity, in contract or in tort, under any federal or state statute or regulation, or in common law, that they, their heirs, successors, attorneys, agents and assigns otherwise would have standing to bring as of the date of this Agreement, including any liability to Relators arising from or relating to the claims Relators asserted or could have asserted in the Civil Actions, except that Relators do not release claims under § 3730(d) for attorneys' fees, costs and expenses. Except as expressly provided in Paragraphs 2 and 22, Relators covenant and agree that, from and after the Effective Date, they shall not bring any action or initiate any proceeding with respect to the foregoing released claims, and they shall not cause, induce, assist, or encourage any other person to assert or pursue any such claims.

5. In consideration of the obligations of HDL in this Agreement and the Corporate Integrity Agreement (CIA) entered into between OIG-HHS and HDL, and conditioned upon HDL's full payment of the Settlement Amount, and subject to Paragraphs 2 (concerning Default), 21 and 22 (concerning bankruptcy proceedings commenced within 91 days of the Effective Date of this Agreement or any payment made under this

Agreement), the OIG-HHS releases and agrees to refrain from instituting, directing, or maintaining any administrative action seeking exclusion from Medicare, Medicaid, and other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) against HDL under 42 U.S.C. § 1320a-7a (Civil Monetary Penalties Law) or 42 U.S.C. § 1320a-7(b)(7) (permissive exclusion for fraud, kickbacks, and other prohibited activities) for the Covered Conduct, except as reserved in Paragraph 8 (concerning excluded claims), below, and as reserved in this Paragraph. The OIG-HHS expressly reserves all rights to comply with any statutory obligations to exclude HDL from Medicare, Medicaid, and other Federal health care programs under 42 U.S.C. § 1320a-7(a) (mandatory exclusion) based upon the Covered Conduct. Nothing in this Paragraph precludes the OIG-HHS from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 8, below. Notwithstanding the foregoing, upon the occurrence of an Event of Default as defined in Paragraph 2, above, OIG-HHS may exclude HDL from participating in all Federal health care programs until HDL pays the Settlement Amount and reasonable costs as set forth in Paragraph 1, above. OIG-HHS will provide written notice of any such exclusion to HDL. HDL waives any further notice of such exclusion under 42 U.S.C. § 1320a-7(b)(7), and agrees not to contest such exclusion either administratively or in any state or federal court. Reinstate to program participation is not automatic. If at the end of the period of exclusion HDL wishes to apply for reinstatement, HDL must submit a written request for reinstatement to OIG-HHS in accordance with the provisions of 42 C.F.R. §§ 1001.3001-.3005. HDL will not be reinstated unless and until OIG-HHS approves such request for reinstatement.

6. In consideration of the obligations of HDL set forth in this Agreement, and conditioned upon HDL's full payment of the Settlement Amount, and subject to Paragraphs 2 (concerning Default), 21 and 22 (concerning bankruptcy proceedings commenced within 91 days of the Effective Date of this Agreement or any payment made under this Agreement). DHA releases and agrees to refrain from instituting, directing, or maintaining any administrative action seeking exclusion from the TRICARE Program against HDL under 32 C.F.R. § 199.9 for the Covered Conduct, except as reserved in Paragraph 8 (concerning excluded claims), below, and as reserved in this Paragraph. DHA expressly reserves authority to exclude HDL from the TRICARE Program under 32 C.F.R. §§ 199.9(f)(1)(i)(A), (f)(1)(i)(B), and (f)(1)(iii), based upon the Covered Conduct. Nothing in this Paragraph precludes DHA or the TRICARE Program from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 8, below.

7. In consideration of the obligations of HDL in this Agreement, and conditioned upon HDL's full payment of the Settlement Amount, and subject to Paragraphs 2 (concerning Default), 21 and 22 (concerning bankruptcy proceedings commenced within 91 days of the Effective Date of this Agreement or any payment made under this Agreement), OPM releases and agrees to refrain from instituting, directing, or maintaining any administrative action against HDL under 5 U.S.C. § 8902a(c) or 5 C.F.R. Part 890, Subpart J, for the Covered Conduct, except as reserved in Paragraph 8 (concerning excluded claims), below, and except if required by 5 U.S.C. § 8902a(b). Nothing in this Paragraph precludes OPM from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 8, below.

8. Notwithstanding the releases given in Paragraphs 3, 4, 5, 6 and 7 of this Agreement, or any other term of this Agreement, the following claims of the United States are specifically reserved and are not released:

- a. Any liability arising under Title 26, U.S. Code (Internal Revenue Code);
- b. Any criminal liability;
- c. Except as explicitly stated in this Agreement, any administrative liability, including mandatory exclusion from Federal health care programs;
- d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;
- e. Any liability based upon obligations created by this Agreement;
- f. Any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services;
- g. Any liability for failure to deliver goods or services due;
- h. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct; and
- i. Any liability of individuals, including current and former employees, agents, shareholders, directors, and officers of HDL.

9. Relators and their heirs, successors, attorneys, agents, and assigns do not and shall not object to this Agreement and confirm that this Agreement is fair, adequate, and reasonable under all the circumstances, pursuant to 31 U.S.C. § 3730(c)(2)(B). Relators

and their heirs, successors, attorneys, agents, and assigns expressly waive the opportunity for a hearing on any objection to this Agreement pursuant to 31 U.S.C. § 3730(c)(2)(B). In connection with this Agreement and the Civil Actions, Relators and their heirs, successors, attorneys, agents, and assigns agree that neither this Agreement, any intervention by the United States in the Civil Actions in order to dismiss the Civil Actions, nor any dismissal of any or all of the Civil Actions, shall waive or otherwise affect the ability of the United States to contend that provisions in the FCA, including 31 U.S.C. §§ 3730(d)(3) and 3730(e), bar Relators from sharing in the proceeds of this Agreement. Moreover, the United States and Relators and their heirs, successors, attorneys, agents, and assigns agree that they each retain all of their rights pursuant to the FCA on the issue of the share percentage, if any, that Relators should receive of any proceeds of the settlement of their claims, and that no agreements between the United States and Relators concerning Relators' share have been reached to date.

10. The Settlement Amount does not include any of Relators' fees and costs, pursuant to 31 U.S.C. § 3730(d), which are to be negotiated separately by HDL and Relators, and will be the subject of a separate agreement.

11. HDL has provided sworn financial disclosure statements (Financial Statements) to the United States and the United States has relied on the accuracy and completeness of those Financial Statements in reaching this Agreement. HDL warrants that the Financial Statements were complete, accurate, and current as of the date such Financial Statements were delivered to the United States and that no material changes have occurred since the last-submitted Financial Statements on March 6, 2015 and the Effective Date of this Agreement. If the United States learns of asset(s) in which HDL had an interest that was

not disclosed or reflected in the Financial Statements or related disclosures to the United States, or if the United States learns of any misrepresentation by HDL on, or in connection with, the Financial Statements, and if such nondisclosure or misrepresentation increases the estimated net worth set forth in the Financial Statements by \$4.7 million or more, the United States may at its option: (a) rescind this Agreement and file suit based on the Covered Conduct, or (b) let the Agreement stand and collect the full Settlement Amount plus one hundred percent (100%) of the value of the net worth increase of HDL previously undisclosed. HDL agrees not to contest any collection action undertaken by the United States pursuant to this provision, and immediately to pay the United States all reasonable costs incurred in such an action, including attorney's fees and expenses. Should the United States elect to rescind this Agreement pursuant to Paragraph 11(a), above, Relators shall have whatever rights they otherwise would have under 31 U.S.C. 3730(c) as of March 30, 2015.

12. In the event that the United States, pursuant to Paragraph 11 (concerning disclosure of assets), above, opts to rescind this Agreement, HDL agrees not to plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any civil or administrative claims that (a) are filed by the United States within 120 calendar days of written notification to HDL that this Agreement has been rescinded, and (b) relate to the Covered Conduct, except to the extent these defenses were available on the Effective Date of this Agreement.

13. HDL waives and shall not assert any defenses HDL may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth

Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action. Nothing in this Paragraph or any other provision of this Agreement constitutes an agreement by the United States concerning the characterization of the Settlement Amount for purposes of the Internal Revenue laws, Title 26 of the United States Code.

14. HDL fully and finally releases the United States, its agencies, officers, agents, employees, and servants, from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that HDL has asserted, could have asserted, or may assert in the future against the United States, its agencies, officers, agents, employees, and servants, related to the Covered Conduct and the United States' investigation and prosecution thereof.

15. HDL fully and finally releases Relators and their successors from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that HDL has asserted or could have asserted against the Relators, related to the Covered Conduct and Relators' investigation and prosecution thereof, and from all liability claims, demands, actions, or causes of action, whether known or unknown, fixed or contingent, in law or in equity, in contract or in tort, under any federal or state statute or regulation, or in common law, that HDL and its successors would have standing to bring as of the date of this Agreement.

16. The Settlement Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment by any Medicare contractor (e.g.,

Medicare Administrative Contractor, fiscal intermediary, carrier), TRICARE or FEHBP carrier or payer, or any state payer, related to the Covered Conduct; and HDL agrees not to resubmit to any Medicare contractor, TRICARE or FEHBP carrier or payer, or any state payer any previously denied claims related to the Covered Conduct, and agrees not to appeal any such denials of claims.

17. HDL agrees to the following:

a. Unallowable Costs Defined: All costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk-1 and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of HDL, its present or former officers, directors, employees, shareholders, and agents in connection with:

- (1) the matters covered by this Agreement;
- (2) the United States' audit(s) and civil investigation(s) of the matters covered by this Agreement;
- (3) HDL's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil investigation(s) in connection with the matters covered by this Agreement (including attorney's fees);
- (4) the negotiation and performance of this Agreement;
- (5) the payments HDL makes to the United States pursuant to this Agreement and any payments that HDL may make to Relators, including costs and attorney fees; and

- (6) the negotiation of, and obligations undertaken pursuant to, the CIA to:
  - (i) retain an independent review organization to perform annual reviews as described in Section III of the CIA; and
  - (ii) prepare and submit reports to the OIG-HHS

are unallowable costs for government contracting purposes and under the Medicare Program, Medicaid Program, TRICARE Program, and FEHBP (hereinafter referred to as Unallowable Costs). However, nothing in Paragraph 17.a.(6) that may apply to the obligations undertaken pursuant to the CIA affects the status of costs that are not allowable based on any other authority applicable to HDL.

b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by HDL, and HDL shall not charge such Unallowable Costs directly or indirectly to any contracts with the United States or any State Medicaid program, or seek payment for such Unallowable Costs through any cost report, cost statement, information statement, or payment request submitted by HDL or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: HDL further agrees that within 90 days of the Effective Date of this Agreement it shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid and FEHBP fiscal agents, any Unallowable Costs (as defined in this Paragraph) included in payments previously sought from the United States, or any State Medicaid program, including, but not limited to, payments

sought in any cost reports, cost statements, information reports, or payment requests already submitted by HDL or any of its subsidiaries or affiliates, and shall request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the Unallowable Costs. HDL agrees that the United States, at a minimum, shall be entitled to recoup from HDL any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously-submitted cost reports, information reports, cost statements, or requests for payment.

Any payments due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by HDL or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on HDL or any of its subsidiaries or affiliates' cost reports, cost statements, or information reports.

d. Nothing in this Agreement shall constitute a waiver of the rights of the United States to audit, examine, or re-examine HDL's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

18. HDL agrees to cooperate fully and truthfully with the United States' investigation of individuals and entities not released in this Agreement. Upon reasonable notice, HDL shall encourage, and agrees not to impair, the cooperation of its directors, officers, and employees, and shall use its best efforts to make available, and encourage, the cooperation of former directors, officers, and employees for interviews and testimony.

consistent with the rights and privileges of such individuals. HDL further agrees to furnish to the United States, upon request, complete and unredacted copies of all non-privileged documents, reports, memoranda of interviews, and records in its possession, custody, or control concerning any investigation of the Covered Conduct that it has undertaken, or that has been performed by another on its behalf.

19. This Agreement is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other person or entity, except to the extent provided for in Paragraph 20 (waiver for beneficiaries paragraph), below.

20. HDL agrees that it waives and shall not seek payment for any of the health care billings covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors based upon the claims defined as Covered Conduct.

21. HDL warrants that it has reviewed its financial situation and that it currently is solvent within the meaning of 11 U.S.C. §§ 547(b)(3) and 548(a)(1)(B)(ii)(1), and that it will, to the best of its ability, remain solvent following payment to the United States of the Settlement Amount. Further, the Parties warrant that, in evaluating whether to execute this Agreement, they (a) have intended that the mutual promises, covenants, and obligations set forth constitute a contemporaneous exchange for new value given to HDL, within the meaning of 11 U.S.C. § 547(c)(1), and (b) conclude that these mutual promises, covenants, and obligations do, in fact, constitute such a contemporaneous exchange. Further, the Parties warrant that the mutual promises, covenants, and obligations set forth herein are intended to and do, in fact, represent a reasonably

equivalent exchange of value that is not intended to hinder, delay, or defraud any entity to which HDL was or will become indebted to on or after the date of this transfer, within the meaning of 11 U.S.C. § 548(a)(1).

22. If within 91 days of the Effective Date of this Agreement or of any payment made under this Agreement, HDL commences, or a third party commences, any case, proceeding, or other action under any law relating to bankruptcy, insolvency, reorganization, or relief of debtors (a) seeking to have any order for relief of HDL's debts, or seeking to adjudicate HDL as bankrupt or insolvent; or (b) seeking appointment of a receiver, trustee, custodian, or other similar official for HDL or for all or any substantial part of HDL's assets, HDL agrees as follows:

a. HDL's obligations under this Agreement may not be avoided pursuant to 11 U.S.C. § 547, and HDL shall not argue or otherwise take the position in any such case, proceeding, or action that: (i) HDL's obligations under this Agreement may be avoided under 11 U.S.C. § 547; (ii) HDL was insolvent at the time this Agreement was entered into, or became insolvent as a result of the payment made to the United States; or (iii) the mutual promises, covenants, and obligations set forth in this Agreement do not constitute a contemporaneous exchange for new value given to HDL.

b. If HDL's obligations under this Agreement are avoided for any reason, including, but not limited to, through the exercise of a trustee's avoidance powers under the Bankruptcy Code, the United States, at its sole option, may rescind the releases in this Agreement and bring any civil and/or administrative claim, action, or proceeding against HDL for the claims that would otherwise be covered by the releases provided in Paragraphs 3, 4, 5, 6 and 7. HDL agrees that (i) any such claims, actions, or

proceedings brought by the United States are not subject to an "automatic stay" pursuant to 11 U.S.C. § 362(a) as a result of the action, case, or proceedings described in the first clause of this Paragraph, and HDL shall not argue or otherwise contend that the United States' claims, actions, or proceedings are subject to an automatic stay; (ii) HDL shall not plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any such civil or administrative claims, actions, or proceeding that are brought by the United States within ninety (90) calendar days of written notification to HDL that the releases have been rescinded pursuant to this Paragraph, except to the extent such defenses were available on December 30, 2011; and (iii) the United States has a valid claim against HDL in the amount of \$100 million, and the United States may pursue that claim in the case, action, or proceeding referenced in the first clause of this Paragraph, as well as in any other case, action, or proceeding.

c. HDL acknowledges that its agreements in this Paragraph are provided in exchange for valuable consideration provided in this Agreement.

23. Upon receipt of the initial payment of the Fixed Settlement Amount described in Paragraph 1, above, and as set forth in Exhibit A hereto, the United States and Relators shall promptly sign and file in the Civil Actions a Joint Stipulation of Dismissal of the Civil Actions pursuant to Rule 41(a)(1), of the allegations asserted against HDL. Furthermore, the Stipulations of Dismissal shall be:

- a. With prejudice as to the Covered Conduct, pursuant to and consistent with the terms and conditions of this Agreement; and
- b. Without prejudice to the United States as to all other claims; and

c. With prejudice to the Relators as to all claims in the Civil Actions.

24. Except as to Relators' fees and costs pursuant to 31 U.S.C. § 3730(d)(1), which are acknowledged as outstanding in Recital G and Paragraphs 4 and 10 herein, each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

25. Each party and signatory to this Agreement represents that it freely and voluntarily enters in to this Agreement without any degree of duress or compulsion.

26. This Agreement is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this Agreement is the United States District Court for the District of South Carolina. For purposes of construing this Agreement, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

27. This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties.

28. The undersigned counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.

29. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.

30. This Agreement is binding on HDL's successors, transferees, heirs, and assigns.

31. This Agreement is binding on Relators' successors, transferees, heirs, and assigns.
32. All parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public; except that the HDL Financial Representations defined in Paragraph 1.b.iii, are subject to the terms and conditions of the May 14, 2013 Confidentiality Agreement between HDL and the United States, as amended.
33. Notices to HDL, as referenced in this Agreement, shall be in writing and delivered via hand-delivery, facsimile, overnight mail, or by registered or certified mail (return receipt requested) to:

Health Diagnostic Laboratory, Inc.  
737 N 5<sup>th</sup> Street, Suite 200  
Richmond, Virginia 23219  
ATTN: Corporate Counsel  
Fax: 1-804-225-0530

Courtesy copies of any such notice may be sent via electronic mail to the foregoing, and by electronic mail, hand-delivery, facsimile, overnight mail, or by regular mail to:

Brien T. O'Connor  
Ropes & Gray LLP  
800 Boylston Street  
Boston, MA 02199  
Fax: 1-617-951-7050

and

Laura G. Hoey  
Ropes & Gray LLP  
191 North Wacker Drive, 32<sup>nd</sup> Floor  
Chicago, IL 60606  
Fax: 1-312-845-5500

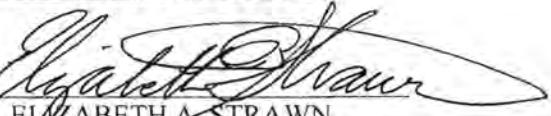
34. This Agreement is effective on the date of signature of the last signatory to the Agreement (the "Effective Date" of this Agreement). Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

\*\*\*\*\* SIGNATURE PAGES TO FOLLOW \*\*\*\*\*

THE UNITED STATES OF AMERICA

DATED: 3/31/15

BY:

  
ELIZABETH A. STRAWN  
MARY CHRIS DOBBIE  
Trial Attorney  
Commercial Litigation Branch  
Civil Division  
United States Department of Justice

DATED: \_\_\_\_\_

BY:

JAMES C. LEVENTIS, Jr.  
Assistant United States Attorney  
Office of the United States Attorney  
District of South Carolina

DATED: \_\_\_\_\_

BY:

JENNIFER A. SHORT  
Assistant United States Attorney  
Office of the United States Attorney  
District of Columbia

DATED: \_\_\_\_\_

BY:

ROBERT K. DECONTI  
Assistant Inspector General for Legal Affairs  
Office of Counsel to the  
Inspector General  
Office of Inspector General  
United States Department of  
Health and Human Services

DATED: \_\_\_\_\_

BY:

BRYAN T. WHEELER  
Acting General Counsel  
Defense Health Agency  
United States Department  
of Defense

THE UNITED STATES OF AMERICA

DATED: \_\_\_\_\_ BY: ELIZABETH A. STRAWN  
MARY CHRIS DOBBIE  
Trial Attorney  
Commercial Litigation Branch  
Civil Division  
United States Department of Justice

DATED: 3/31/15 BY: JAMES C. LEVENTIS, Jr.  
Assistant United States Attorney  
Office of the United States Attorney  
District of South Carolina

DATED: \_\_\_\_\_ BY: JENNIFER A. SHORT  
Assistant United States Attorney  
Office of the United States Attorney  
District of Columbia

DATED: \_\_\_\_\_ BY: ROBERT K. DECONTI  
Assistant Inspector General for Legal Affairs  
Office of Counsel to the  
Inspector General  
Office of Inspector General  
United States Department of  
Health and Human Services

DATED: \_\_\_\_\_ BY: BRYAN T. WHEELER  
Acting General Counsel  
Defense Health Agency  
United States Department  
of Defense

THE UNITED STATES OF AMERICA

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ELIZABETH A. STRAWN  
MARY CHRIS DOBBIE  
Trial Attorney  
Commercial Litigation Branch  
Civil Division  
United States Department of Justice

DATED: \_\_\_\_\_ BY: \_\_\_\_\_  
JAMES C. LEVENTIS, Jr.  
Assistant United States Attorney  
Office of the United States Attorney  
District of South Carolina

DATED: 3/31/15 BY: Jennifer A. Short  
JENNIFER A. SHORT  
Assistant United States Attorney  
Office of the United States Attorney  
District of Columbia

DATED: \_\_\_\_\_ BY: \_\_\_\_\_  
ROBERT K. DECONTI  
Assistant Inspector General for Legal Affairs  
Office of Counsel to the  
Inspector General  
Office of Inspector General  
United States Department of  
Health and Human Services

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Defense Health Agency  
United States Department  
of Defense

THE UNITED STATES OF AMERICA

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ELIZABETH A. STRAWN  
MARY CHRIS DOBBIE  
Trial Attorney  
Commercial Litigation Branch  
Civil Division  
United States Department of Justice

DATED: \_\_\_\_\_ BY: \_\_\_\_\_  
JAMES C. LEVENTIS, Jr.  
Assistant United States Attorney  
Office of the United States Attorney  
District of South Carolina

DATED: \_\_\_\_\_ BY: \_\_\_\_\_  
JENNIFER A. SHORT  
Assistant United States Attorney  
Office of the United States Attorney  
District of Columbia

DATED: 8/14/18 BY: Eric Ventresca, Rosen DeConti  
ROBERT K. DECONTI  
Assistant Inspector General for Legal Affairs  
Office of Counsel to the  
Inspector General  
Office of Inspector General  
United States Department of  
Health and Human Services

DATED: \_\_\_\_\_ BY: \_\_\_\_\_  
BRYAN T. WHEELER  
Acting General Counsel  
Defense Health Agency  
United States Department  
of Defense

THE UNITED STATES OF AMERICA

DATED: \_\_\_\_\_

BY: \_\_\_\_\_

ELIZABETH A. STRAWN  
MARY CHRIS DOBBIE  
Trial Attorney  
Commercial Litigation Branch  
Civil Division  
United States Department of Justice

DATED: \_\_\_\_\_

BY: \_\_\_\_\_

JAMES C. LEVENTIS, Jr.  
Assistant United States Attorney  
Office of the United States Attorney  
District of South Carolina

DATED: \_\_\_\_\_

BY: \_\_\_\_\_

JENNIFER A. SHORT  
Assistant United States Attorney  
Office of the United States Attorney  
District of Columbia

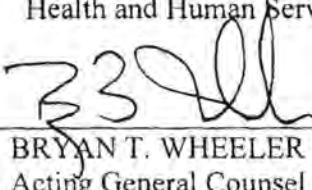
DATED: \_\_\_\_\_

BY: \_\_\_\_\_

ROBERT K. DECONTI  
Assistant Inspector General for Legal Affairs  
Office of Counsel to the  
Inspector General  
Office of Inspector General  
United States Department of  
Health and Human Services

DATED: 3/31/15

BY: \_\_\_\_\_

  
BRYAN T. WHEELER  
Acting General Counsel  
Defense Health Agency  
United States Department  
of Defense

DATED: 3/30/15

BY: Alan P. Spielman  
ALAN P. SPIELMAN  
Assistant Director for Federal Employee  
Insurance Operations  
United States Office of Personnel Management

DATED: 3/30/2015

BY: David Cope  
DAVID COPE  
Debarring Official  
Office of the Assistant Inspector General  
for Legal Affairs  
United States Office of  
Personnel Management

HEALTH DIAGNOSTIC LABORATORY, INC.

DATED: 3/30/15

BY:

  
HEALTH DIAGNOSTIC LABORATORY, INC.

DATED: 3/30/15

BY:

  
BRIEN T. O'CONNOR  
LAURA G. HOEY  
Ropes & Gray LLP  
Counsel for Defendant Health Diagnostic  
Laboratory, Inc.

RELATORS

Chris Riedel - Relator

DATED: 3-30-15

BY: C. Riedel  
CHRIS RIEDEL

DATED: \_\_\_\_\_

BY: \_\_\_\_\_

STEVEN N. BERK  
Berk Law, PLLC  
Counsel for Chris Riedel

DATED: 3-31-15

BY: Niall P. McCarthy  
NIALL P. McCARTHY  
JUSTIN T. BERGER  
ERIC J. BUESCHER  
Cotchetti, Pitre & McCarthy, LLP  
Counsel for Chris Riedel

RELATORS

Chris Riedel - Relator

DATED: \_\_\_\_\_

BY: \_\_\_\_\_  
CHRIS RIEDEL



DATED: 3/3/15  
BY: \_\_\_\_\_  
STEVEN N. BERK  
Berk Law, PLLC  
Counsel for Chris Riedel

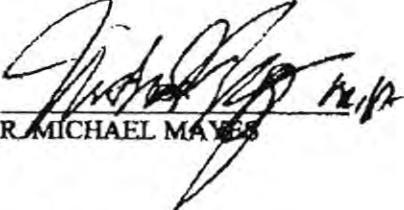
DATED: \_\_\_\_\_

BY: \_\_\_\_\_  
NIALL P. McCARTHY  
JUSTIN T. BERGER  
ERIC J. BUESCHER  
Cotcheti, Pitre & McCarthy, LLP  
Counsel for Chris Riedel

Dr. Michael Mayes - Relator

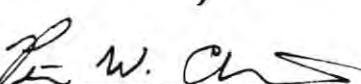
DATED: 3/30/15

BY:

  
DR. MICHAEL MAYES

DATED: 3/31/15

BY:

  
PETER W. CHATFIELD  
Phillips & Cohen, LLP  
Counsel for Dr. Michael Mayes

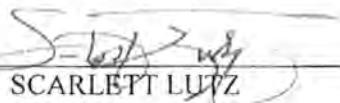
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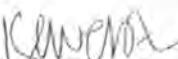
  
WILLIAM A. COATES  
Roe Cassidy Coates & Price, P.A.  
Counsel for Dr. Michael Mayes

Scarlett Lutz & Kayla Webster - Relators

DATED: 3/30/15

BY:   
SCARLETT LUTZ

DATED: 3/30/15

BY:   
KAYLA WEBSTER

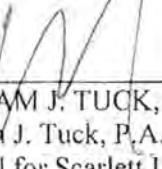
DATED: 3/30/15

BY: \_\_\_\_\_  
MARC S. RASPANTI  
MICHAEL A. MORSE  
PAMELA C. BRECHT  
Pietragallo Gordon Alfano Bosick &  
Raspanti, LLP  
Counsel for Scarlett Lutz & Kayla Webster

DATED: \_\_\_\_\_

BY: \_\_\_\_\_  
JAMES F. WYATT, III  
Wyatt & Blake, LLP  
Counsel for Scarlett Lutz & Kayla Webster

DATED: 3/30/15

BY:   
WILLIAM J. TUCK, Esquire  
William J. Tuck, P.A.  
Counsel for Scarlett Lutz & Kayla Webster

Scarlett Lutz & Kayla Webster - Relators

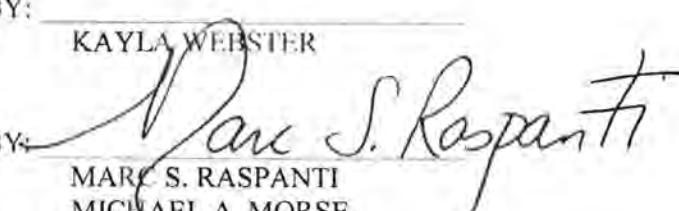
DATED: \_\_\_\_\_

BY: \_\_\_\_\_  
SCARLETT LUTZ

DATED: \_\_\_\_\_

BY: \_\_\_\_\_  
KAYLA WEBSTER

DATED: 3-31-2015

BY: \_\_\_\_\_  
  
MARC S. RASPANTI  
MICHAEL A. MORSE  
PAMELA C. BRECHT  
Pietragallo Gordon Alfano Bosick &  
Raspanti, LLP  
Counsel for Scarlett Lutz & Kayla Webster

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JAMES F. WYATT, III  
Wyatt & Blake, LLP  
Counsel for Scarlett Lutz & Kayla Webster

DATED: \_\_\_\_\_

BY: \_\_\_\_\_  
WILLIAM J. TUCK, Esquire  
William J. Tuck, P.A.  
Counsel for Scarlett Lutz & Kayla Webster

Scarlett Lutz & Kayla Webster - Relators

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BY: \_\_\_\_\_  
SCARLETT LUTZ

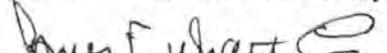
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BY: \_\_\_\_\_  
WILLIAM J. TUCK, Esquire  
William J. Tuck, P.A.  
Counsel for Scarlett Lutz & Kayla Webster

**HDL FIXED PAYMENT SCHEDULE**  
**EXHIBIT A**

	99.56%	0.4407%				
Date	Federal Payments	State Payments	Total Payment	2.25% Interest	Principal	Balance
4/30/2015	973,192.12	4,307.88	977,500.00	352,500.00	625,000.00	47,000,000.00
7/31/2015	881,955.36	3,904.02	885,859.38	260,859.38	625,000.00	45,750,000.00
10/1/2015	2,037,543.22	9,019.28	2,046,562.50	171,562.50	1,875,000.00	43,875,000.00
1/4/2016	2,112,446.04	9,350.84	2,121,796.88	246,796.88	1,875,000.00	42,000,000.00
4/1/2016	1,479,700.04	6,549.96	1,486,250.00	236,250.00	1,250,000.00	40,750,000.00
7/1/2016	1,472,699.77	6,518.98	1,479,218.75	229,218.75	1,250,000.00	39,500,000.00
10/3/2016	1,465,699.51	6,487.99	1,472,187.50	222,187.50	1,250,000.00	38,250,000.00
1/3/2017	1,458,699.25	6,457.00	1,465,156.25	215,156.25	1,250,000.00	37,000,000.00
4/3/2017	2,198,393.70	9,731.30	2,208,125.00	208,125.00	2,000,000.00	35,000,000.00
7/3/2017	2,187,193.28	9,681.72	2,196,875.00	196,875.00	2,000,000.00	33,000,000.00
10/2/2017	2,175,992.86	9,632.14	2,185,625.00	185,625.00	2,000,000.00	31,000,000.00
1/2/2018	2,164,792.44	9,582.56	2,174,375.00	174,375.00	2,000,000.00	29,000,000.00
4/2/2018	3,149,184.98	13,940.02	3,163,125.00	163,125.00	3,000,000.00	26,000,000.00
7/2/2018	3,132,384.35	13,865.65	3,146,250.00	146,250.00	3,000,000.00	23,000,000.00
10/1/2018	3,115,583.72	13,791.28	3,129,375.00	129,375.00	3,000,000.00	20,000,000.00
1/2/2019	3,098,783.09	13,716.91	3,112,500.00	112,500.00	3,000,000.00	17,000,000.00
4/4/2019	4,326,473.66	19,151.34	4,345,625.00	95,625.00	4,250,000.00	12,750,000.00
7/1/2019	4,302,672.76	19,045.99	4,321,718.75	71,718.75	4,250,000.00	8,500,000.00
10/1/2019	4,278,871.87	18,940.63	4,297,812.50	47,812.50	4,250,000.00	4,250,000.00
1/2/2020	4,255,070.97	18,835.28	4,273,906.25	23,906.25	4,250,000.00	-
<b>Total</b>	<b>50,267,332.99</b>	<b>222,510.76</b>	<b>50,489,843.76</b>	<b>3,489,843.76</b>	<b>47,000,000.00</b>	